

32. (New) The radially expandable tape-reinforced tubular vascular graft of claim 30, wherein the radially expandable tape-reinforced tubular vascular graft is capable of undergoing radial enlargement to increase its diameter by at least 5%.

### REMARKS

Reconsideration of the application in view of the above amendments and the following remarks is respectfully requested.

Claims 1-11 were pending in the application. Applicants have cancelled claims 1-11 and added new claims 23-32. Therefore, claims 23-32 are now pending in the application. No new matter has been added by the new claims. Support for the new claims is found throughout the specification. See, for example, the section entitled "Summary of the Invention," which describes a radially expandable tape-reinforced graft that can undergo radial enlargement without tearing or breaking; the section entitled "Radial Shrinkage of The Tape-Reinforced Graft," which describes a radially expandable tape reinforced graft comprised of a graft and a tape that have been reduced in size (e.g. radially shrunk); and page 6, which describes the formation of a longitudinally expanded graft by longitudinal expansion of a PTFE tubular extrudate, for example, by an expansion ratio of 2 to 1.

The cancellation of the pending claims and the addition of the new claims have rendered the claim rejections moot. However, Applicants respectfully offer the following remarks to support the patentability of the new claims in view of the cited prior art.

### CLAIM REJECTIONS UNDER 35 U.S.C. § 102

The Examiner rejected claims 1-6 under 35 U.S.C. § 102 as being anticipated by the admitted prior art described in the application's specification (at ll. 19-29, page 1 and ll. 6-10, page 2). Without agreeing with the propriety of the rejection, Applicants have cancelled the rejected claims and added new claims that clearly distinguish over the described prior art.

The above-cited section of the specification describes prior art tape-reinforced PTFE vascular grafts and, indeed, Applicants admit that tape-reinforced PTFE vascular grafts have been disclosed in the prior art. However, as the specification clearly notes, the prior art tape-reinforced PTFE vascular grafts were not expandable without tearing. Thus, while the prior

art discloses tape-reinforced PTFE vascular grafts, it does not disclose expandable tape-reinforced PTFE vascular grafts, which are the subject of the instant application.

In fact, the inability to expand the prior art tape-reinforced PTFE vascular grafts without tearing had been a constant source of frustration for physicians and surgeons. The tape would inevitably tear when the doctors attempted to expand the graft. Further, the industry had failed in its attempts to manufacture expandable tape-reinforced PTFE vascular grafts until Applicants' invention herein.

Applicants were the first to discover that expandable tape-reinforced PTFE vascular grafts could be made by radially shrinking tape-reinforced vascular grafts. Thus, Applicants discovered that a tape-reinforced PTFE vascular graft that comprises a radially reduced PTFE graft and a reinforcing tape reduced in size is expandable. Additionally, Applicants enabled such an invention by developing a method to manufacture such a tape

The new claims emphasize the distinction over what the Examiner terms "the admitted prior art." For example, new independent claim 23 qualifies the claimed tape-reinforced PTFE graft by providing that "the radially expandable tape-reinforced tubular graft is capable of undergoing radial enlargement to increase its diameter without breaking or tearing of the reinforcing tape." This feature distinguishes the application's claimed graft over the prior art because, as the specification notes, the prior art tape reinforced PTFE grafts were incapable of undergoing more than a minimal amount of radial expansion without tearing of the surrounding tape. See, for example, page 2, ll. 10-19.

Thus, Applicants invention fulfills an important, emerging need for an expandable graft, a need that the prior art grafts were not able to meet. *Id.* at ll. 20-26. Based on the foregoing, Applicants respectfully request that the new claims be allowed to issue over the so-called "admitted prior art."

#### **CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

The Examiner rejected claims 1-11 under 35 U.S.C. 103 as being obvious over the admitted prior art in view of various references (for example, claims 1-4 and 7-8 were rejected under 103 as being unpatentable over the admitted prior art in view of Hiroyoshi, USPN 4678468 and House et al., USPN 5026513).

Based on the foregoing, the admitted prior art cannot be applied to the new claims 23-32. Thus, the admitted prior art cannot be the basis for an obviousness rejection for the new claims. As a consequence, the section 103 rejection as set forth in the instant office action is not applicable to the new claims, which are, therefore, in a condition for allowance.

## DOUBLE PATENTING REJECTIONS

The Examiner rejected various of the claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over certain claims of US Patent nos. 5,928,279 (the “‘279 Patent”) and 5,843,173 (the “‘173 Patent”). In view of the cancelled claims, this rejection is rendered moot.

However, Applicants strongly disagree with the Examiner’s double patenting rejection. The ‘279 Patent is directed to a stented radially expandable graft. Specifically, each of the claims 1, 34 and 35 of the ‘279 Patent claims the combination of a stent with a covering. The new claims, or for that matter the pending claims, do not claim a combination that includes a stent. Therefore, Applicants respectfully submit that the double patenting rejection over the ‘279 Patent is improper and, therefore, should be withdrawn.

Applicants also disagree with the propriety of the double patenting rejection over the ‘173 Patent. The ‘173 Patent contains two claims, both independent. Claim 2 of the ‘173 Patent is directed to a method of endovascular implantation, which clearly has nothing do with either the pending claims 1-11, now cancelled, or the new claims 23-32. Claim 1 is directed to an endovascular system that comprises a graft claimed using product-by-process terminology and an anchoring apparatus. This claim does not make any of the new claims 23-32 obvious. The new claims are product claims, devoid of any process steps.

Therefore, Applicants respectfully submit that the new claims 23-32 are patentably distinct over both the ‘279 Patent and the ‘173 Patent. If the Examiner still deems that a double patenting rejection is proper, Applicants will submit a terminal disclaimer to expedite prosecution. In that case, the Examiner is respectfully requested to telephone the undersigned to discuss the double patenting rejection.

**FEES DUE TO FILE THIS AMENDMENT**

When this application was filed, a fee was paid for a total of 22 claims, with 2 of them being independent claims. The above amendment has resulted in there being a total of 10 claims, with 2 of them being independent claims. Thus, no fee is believed to be due to file this amendment.

**PETITION FOR EXTENSION OF TIME TO RESPOND**

Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for **Three Months** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$930.00 to Deposit Account No. 50-1225 (VAS-4761CONDIV). A duplicate copy of this sheet is enclosed.

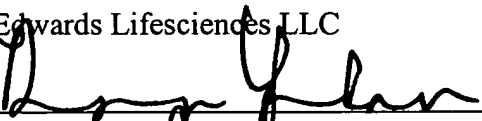
**CONCLUSION**

Accordingly, in view of the above amendments and remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (949) 250-6801.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

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Respectfully submitted,

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